Public Domain

Best Practice Guidance:

Clinical governance of unlicensed medicines and off-label use of licensed medicines in Homecare Services

Version 2.0 9 Sept 2025

Introduction

As homecare services are often part of complex clinical pathways there are homecare medicines pathways or individual patient care plans that are not fully aligned with the Summary of Product Characteristics[1]. Any healthcare professional physically administering medicines must follow the SmPC on dosage, precautions for storage, reconstitution and monitoring throughout the administration unless the unlicensed use is approved and documented. Prescribing, dispensing and administration of unlicensed medicines and unlicensed use of licensed medicines should be considered as a normal element of clinical homecare services. There are some areas of clinical practice where unlicensed use of homecare medicines is routine, e.g. paediatric practice.

Scope

Throughout this document the term unlicensed refers to unlicensed medicines and off-label use of licensed medicines[2].

This document considers the dispensing and administration of medicines in clinical homecare services where the clinical pathway does not follow that envisaged by the manufacturer and regulator as stated in the Summary of Product Characteristics (SmPC).

This guidance does not cover clinical trials which are subject to different regulations and controls.

Guidance for Use of Unlicensed Medicines in Clinical Homecare

Each homecare organisation must have processes that ensure unlicensed medicines are identified and high standards of clinical governance and patient safety are maintained at all times. Implementation of Homecare Medicines Services including routine use of unlicensed medicines will be subject to regular risk assessment and approved by the Chief/Superintendent Pharmacist and the Chief Nurse or equivalent.

The prevalence of unlicensed medicines in clinical homecare services requires clinical and dispensary staff to have heightened vigilance compared to other areas of pharmacy practice to ensure off-label use of licensed medicines is identified and correctly managed. Homecare staff that dispense and administer the unlicensed medicines must have this within their scope of practice.

[1] See Appendix 1 for more information about SmPC
[2] see Appendix 2 for definitions or unlicensed medicines and off-label use

In Homecare Medicines Services where regular use of unlicensed medicines is anticipated, the homecare medicines pathway and/or homecare service specification documents the approval and reasons for use of unlicensed medicine(s).

In Homecare Medicines Services where regular use of unlicensed medicines is not anticipated but is appropriate for one or more individual patients, it is expected that the patient's individual care plan documents the approval and reasons for use of an unlicensed by an appropriate prescriber and/or by the patient's clinical team.

The reasons and decisions relating to one-time use of unlicensed medicines for an individual patient will normally be prescribed by the patient's clinical team via prescription and must be fully documented in the patient's clinical record.

Unlicensed use of medicines in homecare services must be consistent with prevailing regulations and GPhC and CQC/RQIA/Care Inspectorate guidance.

Unlicensed use of medicines in homecare services should be transitioned at the earliest opportunity if an appropriate licensed medicine becomes available.

In all cases, the healthcare professional prescribing, dispensing and/or administrating the homecare medicine must ensure the episode of treatment including unlicensed medicines or off-label use is appropriate. The process of delivering homecare medications to patients is often shared by a number of health care professionals. Their roles includes diagnosis, prescribing, dispensing, administration and clinical monitoring and review. It is important that records are full, complete and appropriately shared and include decisions relating to unlicenced or off-label use of medicines. The homecare organisation's governance processes should provide reasonable assurance to health care professionals that they have discharged their professional duty of care for the patient.

The health care professional has a duty to raise concerns through their organisation's clinical governance system if they believe the unlicensed use is not appropriate or may compromise patient safety. In these cases, the health care professional may seek further independent information from the medical information department of the clinical referring centre or marketing authorisation holder. If the health care professional feels their concerns have not been addressed through the homecare organisation's governance processes, they should seek advice from their professional body and/or consider following the organisations "whistleblowing" process.

Patient Information

Patients must be fully informed about their homecare medicine pathway including full disclosure of unlicensed medicine use and, if appropriate, . The primary responsibility for giving patients information rests with the clinical referring centre. However, it is best practice to provide information to patients using a layered approach to give patients multiple opportunities to understand and ask questions about their treatment. Where patients, or their carer's express concern about any proposed use of unlicensed medicines, healthcare professionals should explain, the reasons why medicines are not licensed for the proposed use. If, after further explanation, the patient still has concerns, the treatment should not continue until the patient has received further counselling from their clinical referring centre. Unless otherwise stated in the approved homecare medicine pathway or in the patient's individual care plan, it is best practice for the patient to be given appropriate information each time the unlicensed elements of the homecare service are provided.

Patient actions or choices that prevent the following of SmPC, approved medicine pathway or their approved individual care plan should be discouraged e.g. the patient chooses not to wait until the registered post administration observation period is over.

Prescribing Unlicensed Homecare Medicines

When prescribing an unlicensed medicine, the prescriber takes responsibility for the unlicensed use of the medicine and for overseeing that patient's care including monitoring and any follow up treatment. The prescriber must be satisfied that:

- an alternative, licensed medicine would not meet the patient's needs
- there is sufficient evidence base and/or experience of using the medicine to demonstrate safety and efficacy
- there is a clear record of the medicine prescribed and the rationale for its use if common practice is not being followed.

In homecare services, "common practice" means the prescriber is prescribing in accordance with an approved homecare medicine pathway and/or approved individual care plan that documents the rationale for use of the unlicensed medicine. It is unlikely that scope of practice of non-medical prescribers within homecare providers will cover use of unlicensed medicines where "common practice" is not being followed.

Reporting Use of Unlicensed Medicines

Where the clinical and medicines homecare service is funded by the manufacturer or marketing authorisation holder, they expect rigorous pharmacovigilance reporting by the homecare provider, and this includes reporting off label use of their licensed medicines.

Within clinical and medicine homecare services there are increasing numbers of novel and complexity homecare medicine pathways not foreseen in the approved SmPC. In these cases, there is particular benefit in ensuring robust recording and reporting of adverse reactions and clinical outcomes which could support optimisation of medicine use, provide evidence for updates to SmPC and therefore improve overall patient care.

Specific Guidance for Types of Unlicenced Use

Governance processes for approval of use of unlicensed medicines in clinical and medicines homecare services are of three distinct types.

1. Unlicensed Homecare Medicines Pathways

Where a homecare medicine pathway uses unlicensed medicine(s), a risk assessment and clinical governance approval process must be followed at implementation, and these must be subject to regular review. This is to ensure regulatory requirements are met and risks to both patient safety and professional conduct standards are minimized. Whilst each healthcare professional involved in the homecare medicine pathway takes responsibility for their own actions, the responsibility for ensuring clinical safety and suitability of the homecare medicine pathway rests predominantly with the clinical governance and approval processes of the clinical referring center.

The unlicensed medicine details or exceptions to the SmPC must be clearly documented including who approved them and when the pathway containing those exceptions will be reviewed. The approval for unlicensed use of medicines within a homecare medicine

pathway must be available to all relevant healthcare professionals delivering the clinical homecare services so they can discharge their individual professional duty to ensure they work within their scope of practice and competency.

2. Pre-approved Individual Patient exceptions

The homecare medicine pathway includes licensed medicines, but there is pre-approved use of unlicensed homecare medicines for an individual patient. The rational and approval relating to the unlicensed use for that patient should be documented in the patient's individual care plan. The patient must receive information about the unlicensed treatment and records must be kept of when and by whom information was provided to the patient. The patient must agree[3] to treatment with the unlicensed medicine prior to the treatment starting. Whilst it is not necessary to provide the information about the unlicensed treatment every subsequent time the medicine is administered or supplied, the patient must be given the opportunity to ask questions and to refuse further unlicensed treatment. During long term treatment with an unlicensed medicine, the patient's understanding of their treatment must be checked regularly and further information provided as necessary.

The Individual Patient's Care Pan should be available to all relevant healthcare professionals so they can fulfil their professional responsibility to ensure the patient is informed but avoid patients being asked repeatedly to detail their understanding of the unlicensed homecare medicine pathway by different healthcare professionals.

3. Ad hoc Individual Patient exceptions

There may be cases where a patient agrees to proceed in accordance with the SmPC compliant homecare medicine pathway, however, full adherence with the approved homecare medicine pathway requirements is not possible. For example, if the patient or carer asks the health care professional to leave before the post administration observation period is over. Where the deviation is at the patient's request, the patient should be asked to sign a "self-discharge note" or similar showing they understand their actions are not recommended.

In any case the healthcare professional should follow the "end of treatment episode" processes, ensuring the patient has information on who to contact if they have concerns about their treatment or feel unwell. It is important that the healthcare professional raises any immediate clinical concerns in accordance with approved clinical escalation processes.

The episode of care documentation must document the information given, decisions taken and must include the reasons for failing to complete the expected treatment in accordance with the approved homecare medicine pathway and information given to the patient or carer.

[3] in homecare services consent means GDPR consent to share personal data; common law "consent" to treatment is referred to as patient agreement to treatment

Disclaimer

NCHA does not warrant or represent that the material in this document is accurate, complete or current. Nothing contained in this document should be construed as medical, commercial, legal or other professional advice. Detailed professional advice should be obtained before taking or refraining from any action based on any of the information contained in this document.

History

Version	Status	Date	Reason for change	Author(s)
v1.0	Draft	22 Jan 2020	New Position Statement	Carol McCall
v1.1	Approved	5 Mar 2020	Update	Carol McCall, NCHA Superintendent Network
v2.0	Approved	11 Sept 2025	Review, update terminology, reformat as guidance	Carol McCall, NCHA Superintendent Network

Appendix 1

What is the Summary of Product Characteristics (SmPC)?

The published SmPC is the primary source of information for health care professionals and explains how to prescribe and use/administer the medicines. Every licensed medicinal product in UK has a marketing authorisation issued by MHRA. SmPCs are written and updated by the manufacturer / marketing authorisation holder based on their research and product knowledge. During the licensing process, the MHRA review and assess the evidence provided by the manufacturer to support the use of the medicinal product. This review results in publication of a Summary of Product Characteristics (SmPC), approved by MHRA, for every licensed medicine available in the UK. Updates to SmPC's may be supported by evidence from clinical trials or post marketing surveillance. When a manufacturer wishes to update a SmPC they must gain approval from MHRA.

Appendix 2

Unlicensed Medicines

Unlicensed medicines do not hold a UK Marketing Authorisation from UK Medicines and Health Regulatory Agency (MHRA). Unlicensed medicines may not be used where a suitable licensed alternative is available.

Compounded medicines are routinely used in homecare services and many of these compounded medicines are unlicensed medicines, but their manufacture is regulated by MHRA under a "manufacturing specials licence" e.g. HPN, i.v. antibiotics.

Some medicines may be licensed in other countries, but not available in the UK market. Import of these medicines is regulated by MHRA.

Off Label Use

Licensed Medications can be prescribed in an unlicensed way, for example,

- for an unlicensed indication,
- for administration of an unlicensed dose,
- for a patient from an unlicensed cohort of patients

For novel medicines, initial indications may be limited in the SmPC, whilst further clinical trials are ongoing. It would normally be expected that prescribing outside the SmPC for a novel medicine is initiated as consultant-led care within a specialist clinical referring centre. For more established medicines, there may be evidence that patients other than those included in the clinical trials, may benefit from the medicine e.g. small patient cohorts for whom clinical trials are prohibitively costly.

Some medicines are routinely used outside the scope of their license, for example in treating children. Pharmaceutical manufacturers do not always test their medicines on children and as a consequence, cannot apply to license their medicines for use in the treatment of children. The use of medicines that have been licensed for adults, but not for children, is often necessary and appropriate in paediatric practice.